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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,033	04/21/2004	Rick J. Tresnak	P06654US00	7437
22885	7590	05/18/2005	EXAMINER	
MCKEE, VOORHEES & SEASE, P.L.C. 801 GRAND AVENUE SUITE 3200 DES MOINES, IA 50309-2721			BUNIN, ANDREW M	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/829,033

Applicant(s)

TRESNAK ET AL.

Examiner

Andrew M. Bunin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☒ Claim(s) 1, 4, 9, 11, 14, and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION*****Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the housing and barrier must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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***Claim Objections***

Claims 1, 4, 9, 11, 14, and 15 are objected to because of the following informalities: These claims include the terms housing and/or barrier, which were not disclosed clearly if at all in the specification and drawings. From viewing the drawings, it seems that the barrier is 32 since it surrounds the carbon dioxide indicator. The housing seems to be section 12 surrounding the first and second tube. However, the barrier and housing need to be disclosed clearly in the specification as well as the drawings.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Babb et al. (US 5197464) (as best understood by the examiner). Babb et al. discloses an adapter comprising a housing 42 containing a first tube 44 and a second tube 48. The housing 42 includes a carbon dioxide indicator 62 within the housing 42, in gaseous communication with the endotracheal tube 26, and isolated from the atmosphere. Babb et al. continues to disclose the adapter's first tube 44 having a tapered insertion end as shown in figures 1 and 2. The

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adapter disclosed has first 44 and second 48 tubes axially aligned. In addition, the housing 42 has an orifice 60 in the perimeter of the second tube 48 with the carbon dioxide indicator 62 covering the orifice and a barrier 50 isolating the carbon dioxide indicator 62 from the atmosphere. As shown in figure 2 and 3, the solution filled cavity 62 is cylindrical, therefore, this indicator covers some of the orifice 60. Babb et al. states, "a typical detector of this character is... 15 millimeters in diameter" (column 13, line 62) which reads on claim 5 describing a second tube having an outside diameter between approximately 12mm - 20mm. As stated above, Babb et al. discloses 15 mm for the outside diameter of a second tube 48, which is approximately 14 mm.

Babb et al. discloses the orifice 60 as being spaced around the second tube 48 and the carbon dioxide indicator 62 surrounds the second tube 48 over the orifice 60 as shown in figure 3. In addition, the carbon dioxide indicator 62 includes a ring of chemically treated colorimetric indicator paper 56. The dictionary defines a membrane as "a thin, pliable layer of tissue covering surfaces or separating or connecting regions...a piece of parchment." Based on this definition, the membrane 56 that is chemically treated is a colorimetric indicator paper 56. Babb et al. also discloses the barrier 50 as a clear ring. Barrier 50 is a section of the housing 42 that is "molded or otherwise fabricated from a clear synthetic polymer such as polyethylene" (column 13, lines 59-61). In addition, the clear ring 50 has a C-shaped cross section defining an aperture for placing the carbon dioxide indicator 62. The cross section of a cylinder such as clear ring 50 has a C-shaped cross section as shown in figure 2.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babb et al. in view of Six (US 5058577) (as best understood by the examiner). Babb et al. discloses an endotracheal tube 26, an adapter 34 having a housing 42 containing a first tube 44 attached to the endotracheal tube 26, and a second tube 48 but does not disclose a stylet placed within the endotracheal tube and the adapter. In addition, Babb et al. doesn't disclose the stylet with a handle that interfaces with the second tube to form a seal. However, Six teaches a "stylet is slidably received within an endotracheal intubation tube" (column 2, lines 18). Six also teaches a stylet 10 with a handle 34 that interfaces with a tube to form a seal as shown in figure 1 and 2. Therefore, it would have been obvious at the time of the invention to one having ordinary skill in the art to include the stylet taught by Six with Babb et al. adapter in order to facilitate insertion of the intubation tube into the airway of a patient.

As for claims 14-16, Babb et al. discloses a carbon dioxide indicator 62 within the adapter housing 42. This housing 42 has an orifice 60 in the perimeter of the second tube 48 with the carbon dioxide indicator 62 covering the orifice

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and a barrier 50 isolating the carbon dioxide indicator 62 from the atmosphere. As shown in figure 2 and 3, the solution filled cavity 62 is cylindrical, therefore, this indicator covers some of the orifice 60. Babb et al. states, "a typical detector of this character is... 15 millimeters in diameter" (column 13, line 62) which reads on claim 16 describing a second tube having an outside diameter between approximately 12mm - 20mm.

Claims 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babb et al. in view of Six (US 5058577). The method steps would have been obvious by the use of the device outlined in the claims. Babb et al. discloses everything except for a bag-valve mask and a stylet within an endotracheal tube and adapter. However, Babb et al. discloses attachment of detector 34 to a ventilator hose 36 and states that "air present from mask ventilation prior to intubation" (column 4, lines 39-40). In addition, applicant has noted that bag-valve mask 48 attached to indicator 102 is considered prior art. Six teaches a "stylet is slidably received within an endotracheal intubation tube" (column 2, lines 18). Six also teaches a stylet 10 with a handle 34 that interfaces with a tube to form a seal as shown in figure 1 and 2. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine a bag-valve mask in the prior art and include the stylet taught by Six with Babb et al. adapter to ventilate a patient and facilitate the insertion of an intubation tube into the airway of a patient.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Babb et al. in view of Six, and further in view of Linder (US 4248236). Babb et al.

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and Six teach everything except a hermetically sealed packaging for an assembly of the endotracheal tube, the adapter, and the stylet. However, Linder teaches an "endotracheal tube with connector, guide, stop, and handle, packaged within a sealed envelope" (abstract, lines 2-4). Therefore, it would have been obvious to use the packaging taught by Linder to hold the endotracheal tube, adapter, and stylet disclosed by Babb et al. and Six in order to provide complete sterility when these medical supplies are not being used.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Babb et al. in view of Six, and further in view of Kaigler et al. (US 5546934). Babb et al. and Six teach everything except the step engaging the bag-valve mask for one ventilation cycle. However, this is considered obvious in the art as well as Kaigler et al. discusses how a bag-valve mask "would then remain in its restored condition until the next bag squeezing operation and such cycle would be repeated as necessary" (column 1, lines 36-38). Therefore, Kaigler et al. teaches that it was well known in the art that there is a step engaging the bag-valve mask for one ventilation cycle.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).



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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 8-13, and 16-20 of copending Application No. 10/981,036 in view of Babb et al. (US 5197464). The claims in copending Application No. 10/981,036 read on all the claims of this application except claims 2 and 3. However, Babb et al. teaches that it is known for an adapter's first tube 44 to have a tapered insertion end as shown in figures 1 and 2. In addition, the adapter disclosed has first 44 and second 48 tubes axially aligned. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the adapter or interconnection claimed in the copending application to have a tapered first tube for allowing it to fit into the end of an endotracheal tube as well as for the first and second tubes to be axially lined in order to line up the ventilating device through the second tube into the first tube as taught by Babb et al.

This is a provisional obviousness-type double patenting rejection.

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**Conclusion**

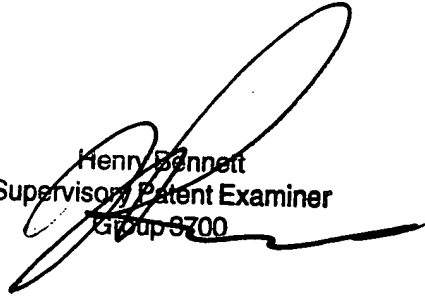
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 5360003, US 6874504, US 4691701, US 4879999, US 6427687, and US 6257236.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Bunin whose telephone number is (571)272-4801. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571)272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
AMB  
5/12/05

  
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